IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Gholam-Reza Zadno-Azizi, et al. Art Unit : 3738
Serial No.: 10/081,569 Examiner : Urmi Chattopadhyay
Filed : February 21, 2002 Conf. No. : 4156
Title : BODY FLUID FLOW CONTROL DEVICE

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF ANTONY FIELDS UNDER 37 C.F.R. §1.132

I, Antony Fields, do hereby declare as follows:

1. I am Vice President of Research and Development for Emphasys Medical, Inc. ("Emphasys"), assignee of the above-captioned patent application, U.S. Application Serial No. 10/081,569 ("the '569 application"). I received my MSc degree in Control Systems from Imperial College of Science and Technology, University of London, in London, England in 1988. I received my M.S. degree in Mechanical Engineering from the Massachusetts Institute of Technology, in Cambridge, Massachusetts in 1985 and my B.S. degree in Mechanical Engineering from University of California, Berkeley in 1983. Since July 2000, I have managed all research and development for Emphasys relating to flow control devices implantable in the lung for the treatment of emphysema

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

January 12, 2006
Date of Deposit

Cecilia Tobin
Signature

Cecilia Tobin
Typed or Printed Name of Person Signing Certificate

and chronic obstructive pulmonary disease. A copy of my *curriculum vitae* is attached hereto as Exhibit 1.

The '569 Application

2. I have reviewed the '569 application, including claims 20-27, which are the only claims now pending in the '569 application.

3. I have reviewed the Office Action issued by the U.S. Patent Office on November 15, 2005, rejecting claims 20-27 of the '569 application. I am aware of the rejection of claims 20-27 under 35 U.S.C. §112, second paragraph.

4. I have reviewed 35 U.S.C. §112, and I am informed that §112 includes an enablement requirement and a written description requirement. I am informed that the enablement requirement means that a specification must provide teachings that permit a person of skill in the art to make and use the invention without having to undertake undue experimentation. I am informed that undue experimentation would be manifest when efforts are required that are considered outside of or beyond the efforts normally expected in the field. Accordingly, routine design choices would not be considered undue experimentation, but the need to undertake comprehensive changes or extensive supplemental efforts to a disclosure would amount to undue experimentation.

5. I am also informed that to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. It is my understanding that an applicant shows possession of the

claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. I am further informed, however, that the subject matter of the claim need not be described literally in order for the disclosure to satisfy the description requirement. By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it.

6. I have reviewed the '569 application with the afformentioned principles in mind.

7. The '569 application describes a flow control device having a valve body 24 and a resilient seal 20 that includes polymeric material capable of sealing within the interior of the body passageway. See, e.g., page 4, lines 3-6 of the '569 application. The resilient seal has a substantially circular cross-section to fit within the body passageway, and an outside diameter of approximately 0.349 inches [8.865 mm], for example. See, e.g., page 4, lines 8-9 and page 7, lines 5-6 of the '569 application. The outside diameter of the resilient seal coincides with the outside diameter of the flow control device. See, e.g., Figure 2 of the '569 application. The flow control device described in the '569 application has a length of approximately 0.60 inches [15.24 mm]. See, e.g., page 7, lines 6-7 of the '569 application.

8. According to the '569 application, the flow control device further includes a frame 30 that is located within the resilient seal. See, e.g., page 5, lines 10-11 of the '569 application. The frame 30 is capable of expanding from an insertion state to an anchor state. In the anchor state, the frame has a diameter that is larger than in the insertion state. See, e.g., page 6, lines 1-6 and page 9, line 21 to page 10, line 1 of the '569 application. In the expanded state, the flow control device fits with interference in the body passageway. See, e.g., page 6, lines 6-7 of the '569 application.

9. According to the '569 application, the flow control device also includes a valve body that provides one-way flow restriction. See, e.g., page 2, lines 13-16 of the '569 application. The valve acts as a one-way valve that opens when a threshold pressure is applied to one end of the valve. See, e.g., page 4, line 22 to page 5, line 4 of the '569 application.

10. When the flow control device is placed in a bronchial passageway, the seal 20 defines a peripheral seal with the interior wall or lumen of the passageway. At one end of the seal 20, a valve support 22 extends inwardly from an attachment to the valve body. This valve support 22 provides a barrier to flow through the resilient seal. No flow can occur across the valve when the valve body is closed.

11. The elastomeric material of the seal 20 can extend around the entire periphery of the flow control device. See, e.g., Figure 1. The seal 20 can have a circular cross-section. See, e.g., Figure 1. It is well-known to those of skill in the art that a bronchial passageway also has a circular cross-section. When the flow control

device is placed in a bronchial passageway, the expandable frame exerts a radially outward pressure against the resilient seal and presses the resilient seal against the inner wall or lumen of the bronchial passageway. Because the resilient seal and the bronchial passageway both have a substantially circular cross-section, the radial pressure on the resilient seal causes the seal to make continuous contact with the lumen of the bronchial passageway, thus forming a continuous seal between the outer wall of the resilient seal and the lumen of the bronchial passageway. In order for fluid to flow past the exterior of the device, there would have to be at least one continuous channel formed between the exterior of the device and the lumen of the bronchial passageway that extends along the length of the entire flow control device. The elastomeric nature of the resilient seal coupled with the flexible nature of a bronchial passageway would not permit such a channel to form. Instead, the exterior of the flow control device would form a continuous seal with the lumen of the bronchial passageway, thus preventing any fluid to flow past the exterior of the flow control device.

12. Therefore, fluid must flow through the valve body 24 in order to flow across the device through the bronchial passageway. When the valve body is closed, the flow control device would necessarily completely block fluid flow through the bronchial passageway, as the sealing contact between seal 20 and the bronchial lumen would prevent fluid from flowing between the seal 20 and the lumen or interior wall of the bronchial passageway. The flow control device has no suture holes or attachment

seams through which air might flow, as the valve body 24, valve support 22, and seal 24 can all be formed of a single piece of flow-blocking material. See page 4, lines 12-13, and Figures 1-3 of the '569 application. Any flow that occurs across the device must be through the valve body, as there is no other passageway in the device through which air can flow. Thus, when the valve is closed, the device blocks air flow through the bronchial passage.

13. As stated above, I am informed that the enablement requirement means that a specification must provide teachings that permit a person of skill in the art to make and use the invention without having to undertake undue experimentation. It is my expert opinion that the '569 application enables the claimed invention in that the specification describes the structural components, shapes, dimensions, and materials that would enable one of skill in the art to make the pulmonic fluid-flow control device and system of claims 20-27. For example, the specification describes the outer body of the flow control device to be formed of a resilient seal 20 that is cylindrical and elastomeric so as to be capable of sealing within the interior of a body duct or passageway. See page 4, lines 3-6 of the '569 application. The flow control device includes an expandable frame 30 that exerts a radially outward pressure against the resilient seal 20 and presses the resilient seal 20 against the inner wall or lumen of the bronchial passageway. Thus, in its expanded stated, the flow control device fits with interference in the bronchial passageway. The flow control device has no suture holes or attachment seams through which air might flow, as the valve body 24, valve support

22, and seal 24 can all be formed of a single piece of flow-blocking material. See page 4, lines 12-13, and Figures 1-3 of the '569 application. These facts are expressly described in the specification as indicated above. In view of the extensive description provided by the specification, it is my expert opinion that the '569 application enables a person of skill in the art to make the pulmonic fluid flow control device and system having a construction that completely blocks air flow through the bronchial passageway as claimed in claims 20-27 without undertaking undue experimentation.

14. It is also my expert opinion that the specification describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Specifically, it is my expert opinion that the flow control device described in the '569 application inherently performs the function of completely blocking air flow through the bronchial passageway when the valve is in the closed configuration for those reasons discussed above. Furthermore, the flow control device has the necessary structure and properties that would completely block air flow through the bronchial passageway when the flow control device is implanted in the bronchial passageway. Because the '569 application discloses a device that inherently performs the aforementioned function and has the properties necessary for performing that function, the application necessarily discloses the function.

15. I declare further that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and

further that these statements and the like are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the Unites States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

1/10/06
Date

Antony Fields

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Experience

Emphasys Medical, Inc., Redwood City CA
Vice President of Research and Development *7/00 – Present*
Managing all research, development, quality and intellectual property activities for small venture funded medical device startup company focused on the development of novel, minimally invasive, devices for the treatment of emphysema and COPD. Joined as first employee prior to funding and incorporation.

Reconstructive Technologies, Inc., Mountain View CA
Vice President of Engineering *7/98 – 7/00*
Director of Engineering *2/98 - 7/98*
Managing all engineering management and development for small venture funded bio-technology startup company focused on the development of novel engineered human tissue replacement therapies. Company has no on-site CEO, so running of the company was performed in conjunction with Vice President of R&D. Achievements include:

- Designed or managed the development of 17 unique prototype devices
- Designed and managed the implementation of automated culture system that can run 48 experiments simultaneously
- Developed sophisticated automation control software and managed revision implementation
- Developed and managed modifications to process control and fluid perfusion system
- Jointly, along with the VP of R&D, performed the following:
  - Planned experiments and set research direction for company
  - Developed company structure and operation protocols
  - Managed all day to day activities of the company, including purchasing, hiring, bookkeeping and employee benefits
  - Presented company progress to Board of Directors every month
  - Recruited and interviewed all temporary and permanent employees during headcount increase from 3 to 14
  - Set salaries and stock options for all employees
  - Set all employee benefits and developed employee handbook
- Worked with outside patent counsel to manage patent portfolio and to prepare two utility patent submissions
- Hired, negotiated contracts with, and managed outside consultants in the following areas:
  - Mechanical Engineering
  - Market Research
  - Clinical Affairs
  - Regulatory Affairs
  - QA / QC
- Managed phone and computer network, and worked closely with outside network consultants
- Managed all outside fabrication vendors as well as in-house contract assemblers
- Purchased or organized leases for numerous pieces of capital equipment
- Tracked total company expenses and cash flow, and projected company burn rate
- Developed purchase order entry and tracking system

IDEO Product Development, Palo Alto CA
IDEO is a full service, turnkey product development consulting firm with seven offices in three countries providing development services in industries ranging from medical technology and office furniture to computers and consumer electronics. Firm grew from 50 employees to 350 during tenure.

Experience (con't)

IDEO Product Development, Palo Alto CA (con't)

Engineering Studio Manager *5/96 - 2/98*

Managed group of 18 mechanical engineers, 3 student interns and one administrative assistant performing contract product development in many industries including medical diagnostics, medical disposables and resposables, surgical equipment, biotechnology, drug delivery systems, consumer electronics, computers, computer peripherals, office furniture, sporting goods, home appliances, and industrial equipment. Responsibilities included:

- Management of $3 to $4 million in revenue, responsibility for studio profit and loss
- Employee and intern recruiting, interviewing and hiring
- Employee career development, salary and bonus distribution
- All aspects of new business development
- Initial client meetings and proposal writing
- Project staffing and planning
- Contract development, project oversight, and maintenance of client contacts
- Design and project management reviews
- Employee design and project management mentorship

Project Manager / Senior Project Manager *6/91-4/96*

Managed development effort and all aspects of client interaction on numerous development projects. Responsibilities included proposal writing, project budgeting, planning and scheduling, all client phone and written communication, design management and reviews, project staffing and coordination, conceptual design development, detailed mechanical design, report preparation and presentation, etc. Most projects involved management of multidisciplinary development, and thus responsible for management of mechanical, electrical, software and manufacturing engineers as well as human factors researchers, industrial designers and interaction designers. Projects managed include:

- Full turnkey development of Dade Behring PFA-100® Platelet Function Analyzer
- Advanced Tissue Science Transcyte™ bioreactor
- Advanced Tissue Science Dermagraft™ bioreactor and growth manifold
- Joint development of Bayer Diagnostics Clinitek® 500 Urine Chemistry Analyzer instrument
- System conceptual development and prototyping for new automated uninalysis instrument for Bayer Diagnostics
- Redesign of line of 3 pagers for AT&T
- Conceptual development and prototyping for advanced vacuum cleaner development
- Radio Frequency LAN Adapter for Alps USA
- Conceptual study and prototyping of line of office products for home workers
- Early development of in-flight trash compactor system for airlines

Senior Mechanical Engineer / Project Manager *4/90-6/91*

Managed technical effort on project to co-develop Horizon® Nxt Modular Infusion System for McGaw Inc. (now B. Braun). Designed and patented flow stop mechanism that successfully avoided numerous competing patents. Organized activities of team of one industrial designer and five mechanical engineers, and managed interface with client. Product is currently best selling infusion pump on the market.

Crystallume, Menlo Park, CA

Senior Mechanical Engineer *6/89-4/90*

Designed microwave and DC plasma powered research reactors for startup attempting to commercialize chemically vapor deposited diamond films. Developed manufacturing processes for laser cutting and polishing of grown diamond films. Performed thermal analyses and worked closely with process and materials engineers to optimize growth processes and parameters.

Orasis, Inc., Oakland, CA

Mechanical Design Engineer *1/89-3/89*

Worked with small start-up company attempting to produce equipment for automated semiconductor inspection based on laser interferometry.

Experience (con't)

Silicon Valley Group Inc., San Jose, CA
Mechanical Design Engineer *2/86-8/87, consulting 11/88-12/88*
Designed improvements to and debugged robotics on a five axis, automated silicon wafer handling system on a vertical thermal reactor. Solved extensive vibration and reliability problems in stepper motor driven axes through a combination of electrical, mechanical and control software changes. Project leader on machine redesign for 200mm wafers. Worked closely with sensors of all kinds, designed sensor interface algorithms and debugged sophisticated wafer edge calibration routines.

Massachusetts Institute of Technology, Cambridge, MA
Research Assistant *9/84-12/85*
Worked with Prof. H Asada on the design and development of a flexible fixturing system for sheet metal airplane wing skins using a six axis IBM RS-1 Cartesian Robot.

Spectra-Physics, San Jose, CA
Manufacturing Engineer *7/83-8/84*
Worked for the Industrial Laser Division and was responsible for designing tooling and assembly processes, solving production problems and correcting design errors on a 1500 watt microprocessor controlled metal working C02 gas transport laser.

Education

Imperial College of Science and Technology, University of London, London, England
MSc degree in Control Systems, Department of Electrical Engineering, September 1988. Thesis under Prof. D Q Mayne on "The Dynamics and Control of a Two Fingered Robot Hand".

Massachusetts Institute of Technology, Cambridge, MA
M.S. degree in Mechanical Engineering, December 1985. Thesis under Prof. H Asada on "The Analysis and Design of a Flexible Robotic Fixturing and Drilling System". Designed award winning servoed robot gripper with internal camera for Automatix Inc. as part of course work.

University of California, Berkeley, CA
B.S. degree in Mechanical Engineering, June 1983. Concentration in Mechanical Design.

Publications

Flexible Fixturing and Automatic Drilling of Sheet Metal Parts Using a Robot Manipulator, A Fields, K Youcef-Toumi and H Asada, presented at the 1986 Japan-USA Symposium on Flexible Automation.

Design of Flexible Fixtures Reconfigured By Robot Manipulators, H Asada and A Fields, presented at the 1985 ASME Winter Annual Meeting.

Patents

Numerous utility patent applications in prosecution based on work at Emphasys Medical, Inc., three confidential utility patents currently under submission based on work at Reconstructive Technologies, Inc.,

5,437,635	Tube flow limiter, safety flow clip, and tube pincher mechanism
5,465,660	Aircraft trash collection and compacting apparatus
5,490,455	Aircraft trash collection and compacting apparatus
D346,172	Combination data converter and radio transmitter unit

Skills

- Extensive experience in both high and low volume manufacturing processes, procedures and documentation.
- Strong background in FDA requirements for medical product development.
- Proficient in MS Excel, Word, Powerpoint and Project, Win95/98/NT/2000/XP OS, SolidWorks, HP ME30/ME10.
- Strong electronics and embedded software background.
- Extensive machine shop and metal fabrication experience.

Background

Raised in San Francisco, California. Avid hiker, swimmer, and skier. Hobbies include furniture making and general woodworking, and life drawing.